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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,798	04/02/2004	Manne Satyanarayana Reddy	BULK3.0-047	9941
45776	7590	11/20/2006	EXAMINER	
DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR, BRIDGEWATER, NJ 08807-2862			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/816,798

Applicant(s)

REDDY ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-7 are pending.
2. Claims 1-5 or 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what does "novel crystalline form VI" or "crystalline form VI with IR, fig.3 etc." mean. Does it mean that the product is 1-benzyl-4-[(5,6-dimethoxy-1-indanon-2-yl)methyl piperidine hydrochloride or does it mean it can have any one of the physical data or all of the physical data.

The nomenclature of crystals as evidenced from the International Union of Crystallography, Bravais lattice or the Strukturbericht designation were attached for applicants' convenience. These guidelines for nomenclature of crystals provided evidence that the instant "crystal Form VI" has not been known to be commonly employed nomenclature with meaning one having ordinary skill in the crystal chemistry to indicate what it is as to provide any limitation to the claims. Therefore, the claims are interpreted to be a crystalline compound of 1-benzyl-4-[(5,6-dimethoxy-1-indanon-2-yl)methyl piperidine hydrochloride in the following rejections.

3. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because it includes multiple categories of invention i.e. a product and a process. It is recommended that the claim be separated into each individual claims for each individual categories of invention.

4. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Please note that the critical starting material for the claim was referred to with an reg. No. 555.MAS/02 which is not available to the public. For operability of the claim, the starting material must be made available to the public at the time the invention was made.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sugimoto et al. US 4,895,841, see the compound 1-benzyl-4-[(5,6-dimethoxy-1-indanon-2-yl)methyl]piperidine hydrochloride at col. 34, example 4.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Imai et al. US 5,985,864.

See col. 7, line 13, crystalline 1-benzyl-4-[(5,6-dimethoxy-1-indanon-2-yl)methyl]piperidine hydrochloride with M.P. 229°C and process of making at col. 8, lines 20-24 or col. 15, example 18.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto et al. '841 in view of Imai et al. '864 further in view of Doelker, Wikipedia, Davidovich or US Pharmacopia.

Determination of the scope and content of the prior art (MPEP §2141.01)

Sugimoto et al. 'disclosed anticipatory compounds of 1-benzyl-4-[(5,6-dimethoxy-1-indanon-2-yl)methyl piperidine hydrochloride as delineated supra. Imai et al. '864 further disclosed that this compound exhibit polymorphism and at least one polymorphic crystalline form has the same melting point i.e. col. 7, line 13 and a process of making crystalline form anticipating the process, col. 8, process 3-5, col. 15, example 18.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art product is that other physical properties of the same compound were provided.

Conventional teaching in the polymorphism disclosed that, "...in the strictest sense, polymorphs are different crystalline forms of the same pure substance..." (Brittain p.2); "more than half of the pharmaceutical compounds exhibit polymorphism" (Doelker summary); "...every compound has different polymorphic forms and that in general the number of forms known for a given compound is proportional to the time and money spent in research on that compound" (Wikipedia), differences in X-ray diffraction may or may not be a true polymorph (Davidovich, US Pharmacopia)

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the above references would find that instant claims prima facie obvious **because** the prior art disclosed the same pure compound 1-benzyl-4-[(5,6-dimethoxy-1-indanon-2-yl)methyl piperidine hydrochloride and its multiple crystalline forms with at least one having the same identical melting point (see section 6, supra). It is also well recognized in the art that X-ray diffraction patterns may have different appearance due to artifacts and small differences (Davidovich) in X-ray diffraction may be due to solvent (US pharmacopia), thus must be carefully evaluated for true new polymorphs.

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A new form of an old product which flow naturally with the properties of such product is normally not patentable in absence of unexpected results. In re Cofer 148 USPQ 268. In the instant case, at least one physical property the melting point is identical. The mere difference in other physical properties which are the innate nature of the known product and may vary from laboratory to laboratory due to different environment, machinery, measuring conditions, artifacts are prima facie obvious variations for such known product.

Further, Imai et al. '864 disclosed identical process of making the crystalline 1-benzyl-4-[(5,6-dimethoxy-1-indanon-2-yl)methyl] piperidine hydrochloride with many effect oriented variations in solvents, templerature etc. The picking and choosing among the variations of operation in crystallization among the choices disclosed in Imai et al. '864 to obtain variation is crystalline properties with innately relative minor differences in X-ray diffraction would be prima facie obvious since such is the expected results conventionally known to one having ordinary skill (Wikipedia, Davidovich, US Pharmacopia).


8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Nov. 13, 2006


Celia Chang
Primary Examiner
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